Nevada State Board of Pharmacy
431 W. Plumb Lane Reno, Nevada 89521
(775) 850-1440 (800)-364-2081 Fax (775) 850-1444

From: Nevada State Board of Pharmacy Inspector

Subject: Self-Evaluation Inspection Process

Medical Devices, Equipment and Gases (MDEG) industry managers and the Board of Pharmacy have jointly adopted the concept of a self-evaluation inspection process for several purposes. First, the inspection process is designed not to incriminate but to educate by providing ample notice and sufficient time to fill out the report. Secondly, you can correct non-compliance matters before inspection.

The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of MDEG services. An inspection evaluation form must be obtained on the website and is to self-assess compliance with Nevada MDEG law.

- I will review the form with you and inspect your facility during the month ***listed on the Inspection Notice.***

Your inspection will occur during normal business hours, at no specific date or time.

The procedure involves the following:

1. At the ***minimum***, print and fill out the self-evaluation form. I cannot evaluate or help you if I don't know what you don't know. Retain the form and have it readily available in a packet ***along with last years inspection report*** so if you are not present when I arrive, your staff can make it available to me.

2. Use the form to guide you through examination of your policies and procedures.

3. I will conduct a review of your operation. My observations, along with your findings will assure understanding and compliance with Nevada law.

4. This plan has been established as a cooperative approach to annual inspections. I would appreciate any input you may have on this joint review process.

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Weekday Hours of Operation: _____ Sat Hours of Operation: _____
Sun Hours of Operation: _____

If the records are located at an address different than the location of the equipment, give the address of the location of the records: (**circle) Records On site / Records Off site address**

_____

Administrator Name _____

NAC 639.694 1. (d) The administrator must b**e** employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week. (the cover letter must be attached to this completed form. Circle yes for compliant and no for non compliant. You may make comments as needed)

PRODUCTS & SERVICES PROVIDED (check all that apply)

☐ Assistive Equipment
☐ Respiratory Equipment
☐ Medical Gases
☐ Life-sustaining Equipment
☐ Enteral Services & Equipment
☐ Orthotics & Prosthetics
☐ Diabetic Equipment & Supplies

Please list of your current employees and a separate list of employees terminated or transferred since your last inspection (or provide a computer printout).

Active Employees Name and Duty (include title where appropriate)	Terminated or Transferred Employees Name and Duty (include title where appropriate)

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General Requirements for all MDEG Registrants NAC 639.6946

Facility clean and maintained in an orderly manner?	Yes	No
Current registration displayed? NAC 639.6942	Yes	No
Restroom with sink with hot and cold running water?	Yes	No
Restroom clean, has hand soap and paper towels, and has sign (employees to wash hands after use)?	Yes	No
City or county business license?	Yes	No
City or county fire code approval?	Yes	No
Proof of general liability insurance (minimum of $1,000,000) Exp. Date: _____		
Does your company have an internet web site?	Yes	No
If so, what is the web address: _____		
Does your company sell any products that require a prescription via the web site/internet?	Yes	No

Inspector's comments:

Records Requirement for all MDEG Registrants

Consumer records kept so that they may be readily retrieved by: NAC 639.695		
Consumer's name	Yes	No
Practitioner's name	Yes	No
Date equipment or service provided	Yes	No
Type of equipment or product	Yes	No
Practitioner orders kept in an orderly and readily accessible manner	Yes	No
Records of communications with health professionals including: NAC 639.6952		
Consumer's physical, functional and associated needs?	Yes	No
Therapeutic or ameliorative objectives for equipment, product, or service provided?	Yes	No
Records of consumer assessment including: NAC 639.6952		
Safety of the environment where equipment will be used	Yes	No
Ability to comply with instructions	Yes	No
Ability to clean and maintain the equipment or product	Yes	No
Records of consumer communications including: NAC 639.6951		
Delineation of the commercially available choices	Yes	No
The set up and use of the equipment or product	Yes	No
The maintenance, servicing, cleaning, and repair of the equipment or product	Yes	No
Does the facility repair equipment on site? NAC 639.6946		
(If yes-have available a repair log that identifies the following:)		
(If no-have available a log that shows where equipment was repaired plus identifies the following:)	Yes	No
Type of equipment	Yes	No
Manufacturer of equipment	Yes	No
Model or model number of equipment	Yes	No
Serial number of equipment	Yes	No
Date of Repair	Yes	No
Specific repair made	Yes	No
Name of person who made the repair	Yes	No
Certification that repair brought equipment back to manufacturer's specification	Yes	No

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Proof that calibration or testing equipment is accurate and maintained according to manufacturer's directions and specifications NAC 639.6946 (attach certifications) Yes No

FDA medical device tracking records kept in orderly and readily accessible manner NAC 639.6949 Yes No

Inspector's comments:

Requirements for Providers of Medical Gases, Respiratory Equipment and CPAP – BIPAP and BIPAP ST. Any company providing respiratory services that require a practitioner order (prescription) needs to have an RT or Nurse on staff or on contract.

NAC 639.6954 **If not applicable skip to next section**

If a nurse is providing respiratory services, the nurse should provide a signed and dated statement that the nurse has been trained in the respiratory modality that the nurse is training a patient to use and that the nurse is qualified to train others in those modalities that the nurse has been trained to provide. If a delivery person is instructing a patient in any respiratory modality, provide a signed and dated statement that the delivery person has been trained by the Respiratory Therapist or Nurse, contracted or employed by the facility, in the modality that the delivery person is instructing the patient to use. NRS 630.047

Stocking only medical grade gases Yes No
Service records regarding all equipment Yes No
Verification that equipment has been checked and is defect free before the equipment is dispensed Yes No
Checking that equipment has not been modified in any way that would affect the effectiveness of the equipment Yes No
Checking that the equipment does not present a fire or shock hazard Yes No
Checking that the equipment has all warning labels and tags Yes No
Records tracking all gases dispensed, including the lot numbers Yes No
Records regarding recalls of gases Yes No
System to track and locate all gases and equipment dispensed <**circle**> Written Electronic
Records of serial numbers and model numbers of all equipment dispensed Yes No
Protocol for cleaning and disinfecting equipment Yes No
Material safety data sheet for solutions and products used in cleaning and disinfecting Yes No
Designated areas for clean and unclean equipment with signs posted Yes No
Designated area for quarantined equipment with signs posted Yes No
Policy and procedure or other documentation for the providing of emergency supply of gases, supplies, and equipment Yes No
Does the facility provide CPAP- BIPAP or BIPAP ST (spontaneous timed) Equipment?

Provide the following information for your Respiratory Therapist(s) or Nurse(s) Providing Respiratory services that require a practitioner order (prescription). Yes No

Name Exp. Date License #

Inspector's comments:

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Special Requirements for Providers of Life Sustaining Equipment (Ventilators) NAC 639.6955
If not applicable skip to next section.

24-hour toll-free number for consumers	Yes	No
Written emergency information and procedure that is attached to the life-sustaining equipment	Yes	No
Policy and procedure or other documentation for the providing of emergency supply of gases, supplies, and equipment.	Yes	No

Inspector's comments:

Special Requirements for Providers of Enteral Services NAC 639.6956
If not applicable skip to next section.

Consumer orientation and written checklist	Yes	No
Manufacturer's instructions provided to consumers	Yes	No
Policy for handling of outdated products	Yes	No

Inspector's comments:

Special Requirements for Providers of Orthotics & Prosthetics
If not applicable skip to next section.

List product categories provided: (i.e.: prosthetic limbs, mastectomy, supports, braces)

Does the facility provide pressurized stockings rated above 20mm/HG?	Yes	No
Orders for stockings filed with consumer's record?	Yes	No
Documentation is available of consumer training in the proper use & maintenance of stockings?	Yes	No

List facility certifications by company & certification category:

(attach list for additional certifications)

Certified fitters names:

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Inspector's comments:

Special Requirements for Providers of Insulin Pumps & Diabetic Supplies
If not applicable skip to next section.

List product categories provided: (i.e.: testing equipment, testing supplies, pumps)

Documentation available of consumer training in the proper use & maintenance of products? Yes No
Does facility supply and service insulin pumps? (If yes list brand & model below) Yes No

Inspector's comments:

Special Requirement for MDEG Wholesalers NAC 639.6957 **(applies only if sell to other providers)**

Maintenance log showing for each piece of equipment:
- Type of equipment Yes No
- Manufacturer Yes No
- Model or model number Yes No
- Serial number Yes No
- Date of repair Yes No
- Specific repair made Yes No
- Name of person who performed the repair Yes No
- Certification that equipment has been returned to manufacturer's specifications Yes No

If repaired equipment cannot be brought back to the manufacturers specifications, proof that the equipment has either been restricted in its use or is removed from service Yes No
Evidence that calibration and testing equipment is accurate Yes No
For scales used to weigh liquid oxygen, certification by the Bureaus of Weights and Measures? Yes No
Records detailing sale or other disposition of equipment? Yes No

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I understand that under NAC 639.694 that as a medical products provider and/or wholesaler that I am required to notify the staff of the Board of Pharmacy of the cessation of employment of the current administrator and of the employment of a new administrator within 3 days of the occurrence. I also understand that I may not operate for more than 10 business days without an administrator.

Remarks:

If you are required to provide any documentation to the inspector via fax or email attach a copy of the document(s) to this inspection form for future review.

Representative's Printed Name

Facility Representative's Signature

Date

Inspector's Signature

Date